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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/509,697 | 06/06/2005 | Yoichiro Ito | E-148-2001/0-US-03 | 2179 |
| 90079 | 7590 | 11/16/2009 | | |
| National Institutes of Health c/o Polsinelli Shugart PC Two Prudential Plaza 180 N. Stetson Ave., Suite 4525 Chicago, IL 60601 | | | EXAMINER FRITCHMAN, REBECCA M | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/509,697 | Applicant(s) ITO, YOICHIRO | |
| | Examiner REBECCA FRITCHMAN | Art Unit 1797 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 12, 20, 21 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 12, 20, 21 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

***Detailed Action
Summary***

This is the Final Office action based on the 10/509697 application attorney remarks dated 08/11/2009.

Claims 1-8, 11, 12, 20, 21, & 25 are pending and have been fully considered.

New claim 25 has been added.

Claim Rejections - 35 USC § 103

1. Claims 1-8, 11, 12, 20, 21, & 25 are rejected under 35 U.S.C. 103(a) as being obvious over NUNOGAKI in US 4968428 in view of ITO in US 4414108.

With respect to Claims 1 & 20, NUNOGAKI teaches of a counter-current chromatography device using stacked flat rings (plurality of plates) driven in rotation. These rings comprise a plurality of cells connected together in a series of ducts engraved on said rings (column 8, lines 41-57 & Figure 12). NUNOGAKI do not teach of the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel. ITO, however, teaches of a flow-through continuous countercurrent chromatography system and more specifically of the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel (the first ends are closer to the control axis of the plate

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than the said second ends)I (Abstract and Figure 7, & column 4, lines 39-50). It would have been obvious to one of ordinary skill in the art to combine the stacked chromatography plates of NUNOGAKI with the interleaved spiral flow channels within the plates of ITO due to the previous problems in the art with coil planet centrifuges (column 1, lines 18-55).

With respect to Claim 2, NUNOGAKI teaches of the plates having a plurality of septa which allow for fluid communication/flow between pairs of plates (column 8, lines 41-68 & column 9, lines 1-11).

With respect to Claim 3, NUNOGAKI teaches of the cassette (with plates) being mounted on a rotor (gear) (abstract).

With respect to Claims 4 ,11, & 12 NUNOGAKI teach of plates for countercurrent chromatography comprising a first surface and a second opposed surface (disc plate and sealing plate) (column 8, lines 41-57 & Figure 12). NUNOGAKI do not teach of the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel. ITO, however, teaches of a flow-through continuous countercurrent chromatography system and more specifically of the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel (the first ends are closer to the control axis of the plate than the said second ends)I (Abstract and Figure 7, & column 4, lines 39-50). More

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specifically, ITO, teaches of a flow-through continuous countercurrent chromatography system and more specifically of the plates having a plurality (at least 2) of interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel (Abstract and Figure 7). ITO also teaches of a first surface and a second opposed surface. It would have been obvious to one of ordinary skill in the art to combine the stacked chromatography plates of NUNOGAKI with the interleaved spiral flow channels within the plates of ITO due to the previous problems in the art with coil planet centrifuges (column 1, lines 18-55).

With respect to Claim 5, ITO teaches of flow channels being formed in the first plate (Abstract and figure 7).

With respect to Claim 6, NUNOGAKI et al. teach of the flow path including grooves into a second plate (inlets and outlets in the uppermost disc plate and the lowermost disc plate (column 8, lines 41-57).

With respect to Claim 7, ITO teaches of the groove extending radially from a point closer to the outer surface of said second opposed surface to a point closer to the control axis of said second opposed surface (Figure 7).

With respect to Claim 8, ITO teaches of the spiral slow channels having a substantially rectangular cross section (column 5, lines 61-68 & column 6, lines 1-3).

With respect to Claim 9, ITO teaches of a flow-through continuous countercurrent chromatography system and more specifically of the plates having a plurality (at least 2)

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of interleaved spiral flow channels formed therein (Abstract and Figure 7). It would have been obvious to one of ordinary skill in the art to optimize the number of included flow channel.

With respect to Claim 10, ITO teaches of spiral flow channels being on one surface and grooves being on a second surface (Claim 10). ITO also teaches of the grooves and channels being radial (Figure 7). It would be obvious to one of ordinary skill in the art to optimize the number of included grooves with respect to the number of included flow channels.

With respect to Claim 21, ITO et al. teach of a groove being on first and second sides of one plate (Claim 10).

With respect to Claim 25, ITO teaches of feed tubes and return tubes for phases A & B (column 4, lines 39-50). In the examiner's understanding, this means that the tubes must be in "fluid communication" with each other as currently claimed to allow for the movement of fluid(outer end to inner end)(feed and return).

Response to Arguments

Applicant's arguments filed 08/11/2009 have been fully considered but they are not persuasive.

With respect to the argument that the multiple interleaved fluid coils of ITO are not connected together:

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

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(i.e., the multiple interleaved fluid coils are not connected together) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant solely claims that the second end of the first spiral flow channel is in fluid communication with the first end of the second spiral flow channel. ITO teaches of feed tubes and return tubes for phases A & B (column 4, lines 39-50). In the examiner's understanding, this means that the tubes must be in "fluid communication" with each other as currently claimed to allow for the movement of fluid (feed and return).

Also, as evidenced by YOSHIO in Japanese patent application 61288154 A (as cited on IDS dated (07/01/2005), connected plates of flow tubes were priory known (abstract) and used for chromatography.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim, Vickie can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

R.F.